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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/914,352	12/14/2001	Jens Mattsson	53631-65307	3692

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EXAMINER

NAVARRO, ALBERT MARK

ART UNIT	PAPER NUMBER
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1645

DATE MAILED: 09/16/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/914,352

Applicant(s)

MATTSSON, JENS

Examiner

Mark Navarro

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 June 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,4,6,7,10,11,14,15,17-26 and 28-30 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 18,19 and 29 is/are allowed.
- 6) ☒ Claim(s) 1,4,6,7,10,11,14,15,17,20-26,28 and 30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Applicants amendment filed June 22, 2005 has been received and entered. Claims 2-3, 8-9, 12-13, 16 and 27 have been canceled. New claims 28-30 have been added. Consequently, claims 1, 4, 6-7, 10-11, 14-15, 17-26, and 28-30 are pending in the instant application.

Claim Rejections - 35 USC § 112

1. The rejection of claims 1, 4, 6-7, 10-11, 14-15, 17, 22-26 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is maintained. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Additionally this rejection is applied to newly added claim 28 and 30.

Applicants are asserting that claims 18-21 and 28-30 have been amended to a protein consisting of amino acids 1-83 of SEQ ID NO: 2, and that the present specification shows possession of such a peptide. Applicants further assert that the fundamental factual inquiry is whether the specification conveys with reasonable clarity to those skilled in the art that, as of the filing date sought, applicant was in possession of the invention as now claimed. Applicants further assert that a sequence listing mistake was made when the Swedish application was proceeded with as a PCT application.

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Applicants arguments have been fully considered but are not found to be fully persuasive.

First, Applicants assert that claims 18-21 and 28-30 have been amended to a protein consisting of amino acids 1-83 of SEQ ID NO: 2, and that the present specification shows possession of such a peptide. While these assertions are correct, Applicants claim 28 does not recite that which Applicants assert. Claim 28 is directed towards a protein "comprising" the sequence of amino acids 1-83 of SEQ ID NO: 2. As such, the previous rejection is maintained for reasons of record. Likewise claim 30 is directed to a nucleic acid encoding for a protein consisting of amino acids 1-83 of SEQ ID NO: 2, this language allows for upstream and downstream nucleotides from the fragment disclosed. Applicants specification is silent as to the nature of these regions, as such the written description requirement is again found to be lacking in the instant disclosure. Note amendment of the claim to recite an isolated nucleic acid consisting of a nucleic acid sequence which encodes a peptide consisting of amino acids 1-83 of SEQ ID NO: 2, would be sufficient to overcome this rejection. Applicants amendments to claims 18-21 and new claim 29 are sufficient to overcome this rejection.

Second, Applicants assert that the fundamental factual inquiry is whether the specification conveys with reasonable clarity to those skilled in the art that, as of the filing date sought, applicant was in possession of the invention as now claimed. However, this is the precise basis of the written description rejection. Applicants have disclosed only a fragment of a full length protein. Without disclosure of the full length protein, Applicants written description is only adequately described for the identified

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fragment. *The Regents of the University of California v. Eli Lilly* (43 USPQ2d 1398-1412), the court held that a generic statement which defines a genus by only their functional activity does not provide an adequate written description of the genus. The court indicated that while Applicants are not required to disclose every species encompassed by a genus, the description of a genus is achieved by the recitation of a **representative number** of DNA molecules, usually defined by a nucleotide sequence, falling within the scope of the claimed genus. (Emphasis added). In contrast, Applicants have disclosed only one “consisting of” fragment of a protein, as such the written description requirement is found to be lacking for claims which encompass the full length protein.

Finally, Applicants assert that a sequence listing mistake was made when the Swedish application was proceeded with as a PCT application. However, a Swedish application is simply not part of the application as “originally filed.” Applicants could have just as easily determined the error to have been in the Swedish application and corrected in the US’ filed application. In any event, the Swedish application is not part of the originally filed application and cannot be used to satisfy the written description requirement.

For reasons of record as well as the reasons set forth above, this rejection is maintained.

2. The rejection of claims 20-21 under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an immunogenic composition consisting of SEQ

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ID NO: 2 does not reasonably provide enablement for methods of **treatment** comprising administering compositions consisting of SEQ ID NO: 2 is maintained.

Applicants are asserting that the amendment to the claims overcomes the rejection.

Applicants arguments have been fully considered but are not found to be fully persuasive.

As set forth previously by Plotkin et al, those of skill in the art recognize that it is unpredictable whether a single protein derived from a pathogen will elicit protective immunity. This is the type of immunity required by Applicants claims 20-21, i.e., for the **treatment** of a disease associated with mites. Thus, Factors 1, 4, 5 and 7 are all addressed by this teaching. Furthermore, Applicants specification provides no working examples of any treatment. (Factors 1 and 3).

Facts that should be considered in determining whether a specification is enabling, or if it would require an undue amount of experimentation to practice the invention include: (1) the quantity of experimentation necessary to practice the invention, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. See In re Wands, 858 F.2d 731,737, 8 USPQ2d 1400, 1403 (Fed. Cir. 1988). The Federal Circuit has noted, however, that only those factors that are relevant based on the facts need to be addressed. See Enzo Biochem. Inc. v. Calgene, Inc. 188 F.3d 1362, 1371, 52 USPQ2d 1129, 1135 (Fed. Cir 1999).

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The specification provides insufficient guidance of how to use the claimed polypeptides as a pharmaceutical for the treatment of disease. It is well recognized in the art that it is unclear whether a single protein derived from a pathogen will elicit protective immunity. Ellis, R. W. (see Chapter 29 of "VACCINES" [Plotkin, S.A et al.,(ed.), published by W.B. Saunders Company (Philadelphia) in 1988, especially page 571, 2nd full paragraph] exemplifies this problem in the recitation that "The key to the problem (of vaccine development) is the identification of that protein component of a virus or microbial pathogen that itself can elicit the production of protective antibodies ...and thus protect the host against attack by the pathogen."

In view of the lack of guidance, lack of examples, and lack of predictability associated with regard to producing and using the proteins encompassed in the scope of the claims one skilled in the art would be forced into undue experimentation in order to practice broadly the claimed invention.

For reasons of record, as well as the reasons set forth above this rejection is maintained.

Claim Rejections - 35 USC § 102

3. The rejection of claim 6 under 35 U.S.C. 102(b) as being anticipated by Birkett is withdrawn in view of Applicants amendment.
4. The rejection of claims 14-15 under 35 U.S.C. 102(e) as being anticipated by Hsu is withdrawn in view of Applicants amendments.

Claim Rejections - 35 USC § 112

5. The rejection of claims 14-15 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn in view of Applicants amendment.

6. The rejection of claims 14-15 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn in view of Applicants amendment.

Claims 18-19 and 29 are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of


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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark Navarro whose telephone number is (571) 272-0861.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (571) 272-0864. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Mark Navarro
Primary Examiner
September 6, 2005